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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,312	09/25/2006	Kevin Wickline	US040174US	6113

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Briarcliff Manor, NY 10510-8001

EXAMINER

GUPTA, VANI

ART UNIT	PAPER NUMBER
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3777

NOTIFICATION DATE	DELIVERY MODE
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01/05/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/599,312	Applicant(s) WICKLINE ET AL.	
	Examiner VANI GUPTA	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-18 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-18 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Sutton (US 7,081,113 B2).

Regarding claims 1 and 9, Sutton discloses an ultrasonic probe (*1*) comprising:
transducer (*51*) located at a distal end of the probe (*fig. 1*), the transducer capable of being moved within a chamber to scan an image region outside the probe;
a fluid chamber (*31*) capable of enclosing the transducer within the probe;
an acoustic fluid which is highly transmissive of ultrasound located in the fluid chamber (col. 7, ll. 45 – 53); and
a thin-walled volume compensation balloon formed of a high performance thermoplastic material, and located completely within the probe (“expandable devices,” *fig. 4, (323) and (325)*; col. 6, ll. 56 – 58), capable of being in fluid communication with the fluid chamber, the volume compensation balloon capable of containing a small fraction of the fluid of the fluid chamber at room (ambient) temperature (*col. 7, ll. 29 – 47; col. 7, l. 5 – 44; col. 9, ll. 3 – 33*).

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With respect to Claim 9, the thin-walled balloon is capable of exhibiting a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 1.0 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation.

2. Claims 2 – 5 and 7 – 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Maguire et al. (US 2003/00883653 A1).

Regarding claims 2, 7, and 9, Maguire et al. (hereinafter Maguire) suggests an ultrasonic probe comprising:

a transducer ([0154 – 0155], [0229]) located at a distal end of the probe, the transducer capable of being moved within a chamber to scan an image region outside the probe, comprising:

a fluid chamber (**201**) capable of enclosing the transducer within the probe (paragraph [0154]);

an acoustic fluid capable of being highly transmissive of ultrasound located in the fluid chamber ([0126] and [0136]); and

a thin-walled volume compensation balloon located completely within the probe (when in deflated or unexpanded form; and still within catheter as it would be surrounded by “non-elastomeric” regions of catheter (**figs. 10A – 10C; (1010)**), formed of a high performance thermoplastic material capable of being in fluid communication with the fluid chamber, the volume compensation balloon capable of containing a small fraction of the fluid of the fluid chamber at room (ambient) temperature, wherein the thin-walled balloon is formed of a non elastomeric thermoplastic material ([0160] and [0169 – 0171]).

With respect to Claim 7, the non-elastomeric thermoplastic material comprises PET polymer ([0144]). **With respect to Claim 9**, the thin-walled balloon is capable of exhibiting a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 1.0 atmospheres; and a thermal stability which does not significantly decrease compliance at low temperatures of operation ([0147]).

Regarding claims 3 – 5, Maguire discloses the ultrasonic probe of Claim 2, wherein the thin-walled balloon is capable of exhibiting a low permeability to the acoustic fluid (**fig. 2**; [0140]); wherein the thin-walled balloon exhibits a high compliance over the designed temperature range of transport and use; and wherein the thin-walled balloon is capable of exhibiting a high thermal stability and is capable of being operated at or below the glass transition temperature for the thermoplastic material.

Regarding Claim 8, Maguire suggests the ultrasonic probe of Claim 7, wherein the thin-walled balloon is capable of exhibiting high burst strength.

3. Claims 10 – 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Driscoll, Jr et al. (US 5,882,302).

Regarding claims 10, 13, and 14, Driscoll, Jr. et al. (hereinafter Driscoll) suggests an ultrasonic probe for three dimensional imaging comprising:

- a probe body enclosing a fluid chamber (figs. 3 – 5);
- an array transducer (**45**) capable of being movable (or movably mounted) within the fluid chamber;
- a drive mechanism coupled to the array transducer to move the array transducer during scanning;

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an acoustic fluid located within the fluid chamber (*figs. 3 – 5*; col. 8, ll. 16 – 22 and 59 – 65); and

a volume compensation balloon (38) located completely within the probe, as in completely integrated with the probe body, capable of being in fluidic communication with the fluid chamber (*fig. 3, (36)*), the balloon being formed of a substantially non elastic material, high performance thermoplastic such as PET (col. 9, ll. 13 – 23) and capable of being partially expanded at room temperature.

Regarding Claim 11, Driscoll suggests the ultrasonic probe of Claim 10, wherein the balloon is capable of being approximately half filled with acoustic fluid at room temperature. Applicant should note that this feature refers to intended use of the apparatus and does not positively recite *structurally* limiting feature.

Regarding Claim 12, Driscoll suggests the ultrasonic probe of Claim 11, wherein the balloon is capable of containing less than 20% of the fluid of the fluid chamber at room temperature. Applicant should note that this feature refers to *intended use* of the apparatus, namely the balloon, and does not positively recite *structurally* limiting features.

Regarding claims 15 and 16, Driscoll's balloon wall is capable of being compliant substantially constant over a design temperature range of transport and *use*; wherein the design temperature range of *use* extends below 0°C. Applicant should note that these features refers to *intended use* of the apparatus and does not positively recite *structurally* limiting features.

Regarding Claim 18, Driscoll suggests a shaft (32) designed for inherent intracavity *use* of the probe (col. 6, ll. 64 – 67). Applicant should note that “intracavity use” refers to intended

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use of the apparatus and does not positively recite *structurally* limiting features, which in any case, Driscoll teaches.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire as applied to Claim 2 above.

Regarding Claim 6, Maguire teaches each and every limitation of the claim, as discussed above in reference to claim 2.

However, Maguire differs from Claim 6 in that Maguire does not teach that the acoustic fluid comprises silicone oil.

However, it would be have been obvious matter of design choice to include a silicone oil for the acoustic fluid, since applicant has not disclosed that particularly providing silicone oil as per paragraph [0014] in present disclosure) solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the fluid provided by Maguire (paragraph [0126] of Driscoll's disclosure).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Maguire before one at the time the invention was made, to modify the acoustic fluid

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teachings of Maguire to include silicone oil to maximize on performance and results of Maguire's apparatus.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll.

Regarding Claim 17, Driscoll teaches each and every limitation of the claim, as discussed above in reference to claim 11.

However, Driscoll differs from Claim 17 in that Driscoll does not teach the ultrasonic probe as claimed, wherein the wall thickness of the balloon is less than 1.0 mil.

Nonetheless, as it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a balloon with wall thickness of less than 1.0 mil, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only skill in the art.

Furthermore, Examiner has noted that the disclosure of the present application has not provided a criticality for utilizing a balloon comprising wall thickness within these specifications (i.e. >1.0 mil). Applicant should note that differences in such concentration would not support the patentability of subject matter encompassed by the prior art unless there has been evidence indicating such concentration would be critical; and where only general conditions of a claim have been disclosed in the prior art, it would not be inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Additionally, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which would achieve a recognized result, before the determination of the optimum or workable ranges of said variable could be characterized as routine experimentation.

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See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Since Driscoll has not recognized that balloon performance efficiency is a function of the thickness of the balloon wall, optimizing this weight is not recognized in the art to be a result-effective variable. See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, Driscoll provides an apparatus wherein the wall of the balloon is capable of exhibiting a low permeability to the acoustic fluid. Applicant should note that this feature refers to intended use of the apparatus and does not positively recite *structurally* limiting feature.

Response to Arguments

6. Applicant's arguments and claim amendments, see page 7, filed November 9, 2011, with respect to 35 U.S.C. §112 rejections of present claims have been fully considered and are persuasive. The rejection of these has been withdrawn.

7. Applicant's arguments filed November 9, 2011 with respect to art claims have been fully considered but they are not persuasive.

In response to Applicant's arguments with respect to claims 1 and 9, Examiner disagrees respectfully and directs Applicant to the rejections above. Furthermore, Applicant is referring to intended use of Sutton's device. Applicant is reminded that a recitation of the intended use of the claimed invention must result in a (non-obvious and patentably novel) structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, it meets the claim.

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Please refer to the rejections above to see how Sutton meets the amended portions of the claims.

Claim 9 recites features or limitations pertaining to functionality, which Sutton is *capable of* meeting or performing.

With respect to claims 2 – 5 and 7 – 9, please refer to response(s) above. This refers to Macquire's teachings as well. Please refer to the rejections above to see how Macquire meets the amended portions of the claims.

In response to Applicant's arguments with respect to Claim 6, Examiner disagrees respectfully; Maguire does suggest an ultrasonic probe comprising a transducer ([0154 – 0155], [0229]) located at a distal end of the probe, the transducer capable of being moved within a chamber to scan an image region outside the probe.

With respect to claims 10 – 16 and 18, please refer to response(s) above. This refers to Driscoll's teachings as well. Please refer to the rejections above to see how Driscoll meets the amended portions of the claims.

In response to Applicant's arguments with respect to claims 10 and 17, claims do not indicate any quantitative degree for “partially expanded” volume compensation balloon. The claim does not also suggest any quantitative amount for fluid within the transducer region. As such, Driscoll reads on the claim.

Conclusion

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/V. G./

Examiner, Art Unit 3777

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777